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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,081	04/06/2001	Satoru Oi	2559US0P	2326

23115 7590 05/18/2004

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC  
INTELLECTUAL PROPERTY DEPARTMENT  
475 HALF DAY ROAD  
SUITE 500  
LINCOLNSHIRE, IL 60069

EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

### Office Action Summary

Application No.

09/807,081

Applicant(s)

OL ET AL.

Examiner

Binta M. Robinson

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9, 13-15, 17, 18, 21 and 24-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 2, 3, 4, 5, 6, 7, 9, 21, 24, 26, 27, 28, 29, 30, 32 is/are allowed.
- 6) ☒ Claim(s) 17, 18 and 25 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____   | 6) <input type="checkbox"/> Other: ____                                     |

### **Detailed Action**

Claims 1, 2, 3, 4, 5, 6, 7, 9, 13, 14, 15, 17, 18, 21, 24, 25, 26, 27, 28, 29, 30, 31, 32 are now pending in the application.

The restriction requirement made in the paper 6. is modified to read on claims 1, 2, 3, 4, 5, 6, 7, 9, 13, 14, 15, 17, 18, 21, 24, 25, 26, 27, 28, 29, 30, 31, 32 drawn to the compound of formula I in claim 1 wherein Y is equal to 2 H atoms, D is as claimed, E is as claimed, G is as claimed, Z is as claimed, A is a phenyl ring optionally substituted as claimed, B is a phenyl ring which is optionally substituted or a cycloalkane ring, L is an alkyl group optionally substituted as claimed, but not optionally interrupted by O or S, or a chemical bond, X is as claimed, R<sub>2</sub> is an optionally substituted amino group, the method of treating with this compound, a method of producing this compound according to formula Ia, and a pharmaceutical composition containing said compound,. The applicant traverses the election/restriction requirement asserting that the group I constructed at paper no. 6 does not include the elected invention. The applicant then went on to "elect" group II, although the examiner informed the applicant in the election/restriction requirement mailed 4/26/02, that the election of species was only for the purposes of constructing a group I invention that would be searched and examined. Contrary to the applicant's assertion that the elected species falls into Group II, the elected species does not fall into group II. Group II is revised to include all other subject matter not in the revised group I and will be held to be nonelected subject matter and will not be examined. The restriction/election is not drawn only to one species as the applicant alleged, but

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is now drawn to modified group I, which now encompasses the elected species. The applicant also traversed the limiting of group A to a carbocyclic ring since the applicant did not use this language in the specification. A carbocyclic ring is by definition a ring in which the only ring atoms are C atoms. A homocyclic ring shares the same definition as a carbocyclic ring. So the examiner is willing to alter the definition of A to be a homocyclic ring optionally substituted as claimed.

A restriction is based on the basis that the compounds lack a common core. For example, a compound sharing a core that is similar to the core of the instant compound wherein Y is H, A is phenyl, X is O, B is Phenyl can have a utility as selective cathepsin S inhibitors. (See Ca 138:24322, RN 4477860-85-8). However, when you have a compound sharing a core that is similar to the instant compound, but Y is H, the utility changes such that the compound is useful in desensitizing individuals against contact sensitivity to haptens. (See Ca 124:146864, RN 173525-55-8)

The restriction requirement is FINAL.

**(new rejections)**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-18, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 17, page 8 of the remarks filed 2/17/04, lines 1 and 8, and in claim 18, page 8, lines 1 and 8, the phrase "wherein the symbols have the same

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meanings as in claim 1" is indefinite because it is not clear as to what symbols the applicant is referring to. All radicals and symbols within a claim must be defined at that claim.

B. In claim 17, page 9, line 2, the phrase "wherein the symbols have the same meanings as above" is ambiguous. Is the applicant referring to the symbols having the same meanings in preceding claims, within the same claim or in the specification? All radicals and symbols must be defined at claim 17.

C. In claim 25, page 14, line 1, and in claim 31, page 19, line 1, the phrase "complications of diabetes" is ambiguous. Treating complications of diabetes is not the same thing as treating diabetes. What complications of diabetes is the applicant referring to?

Claims 1, 2, 3, 4, 5, 6, 7, 9, 21, 24, 26, 27, 28, 29, 30, 31, 32 are allowable as they read on the elected subject matter.

The IDS filed 4/6/01 has been reviewed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699.

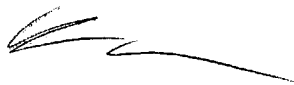
A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.



BMR  
May 17, 2004



JOHANN RICHTER  
SUPERVISORY PATENT EXAMINER  
GROUP 1200



UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,081	04/06/2001	Satoru Oi	2559USOP	2326

23115 7590 04/26/2002

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC  
INTELLECTUAL PROPERTY DEPARTMENT  
475 HALF DAY ROAD  
SUITE 500  
LINCOLNSHIRE, IL 60069

EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 04/26/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/807,081

Applicant(s)

OL ET AL.

Examiner

Binta M. Robinson

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other.



## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Examples 1 through 245 on pages 104 to 405

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-23.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species lack a common core.

The election of species will be used as a reference point for the examiner to

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create a natural genus based on a liberal interpretation of the doctrine of legal and chemical equivalence and restriction will be required under 35 U.S.C. 121 and 372.

A telephone call was made to Mark Chao on 3/20/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

*BMR*  
*4/24/02*

*Alan L. Rotman*  
ALAN L. ROTMAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600